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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,655	02/01/2002	Bruno Giannetti	054756-5003-00	1818

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/061,655	Applicant(s) GIANNETTI ET AL.	
	Examiner Jessica R. Baxter	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 September 2005 has been entered.

Oath/Declaration

2. The oath or declaration was objected to in the office action of 17 December 2004 for being defective. Correction is noted and the objection is withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 17, 18, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,769,899 to Schwartz et al.

Schwartz discloses a cartilage repair structure consisting essentially of: (a) a cell-free, bioresorbable matrix comprising hyaluronic acid; and (b) chondrocyte cells adjacent a surface of said matrix; wherein said matrix includes a porous surface and the chondrocytes are adjacent the porous surface of the matrix (Column 7, lines 4-30). The cells are clearly held onto the surface of the matrix in order to permit vascular invasion.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. '899.

Schwartz discloses the claimed invention except for the chondrocyte cells being autologous (claim 19), or allogenic (claim 20), or xenogenic (claim 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the structure of Schwartz et al. with the chondrocyte cells being autologous, or allogenic, or xenogenic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In *re Leshin*, 125 USPQ 416.

Response to Arguments

7. Applicant's arguments filed 20 June 2005 have been fully considered but they are not persuasive.

8. Applicant argues that Schwartz et al. '899 do not disclose that the chondrocytes are adjacent to a surface of the matrix. However, Schwartz discloses that the cells may be overlaid into the material (Column 7, lines 26-28). An overlaid material is a material that is laid over another material by definition. This term clearly indicates that the cells are adjacent the surface of the matrix.

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9. As stated in the office action of 17 December 2004, applicant argues that the recitation of "consisting essentially of" limits the claims to just a hyaluronic acid matrix and chondrocytes adjacent thereto, it is noted that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claim invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA). In the instant case the Schwartz et al. structure is not affected by the delivery unit, i.e. it does not change the basic and novel characteristics of the structure. Furthermore, for the purposes of searching under 35 U.S.C. 102 and 103, "consisting essentially of" will be construed as equivalent to "comprising" PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. Moreover, if applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). In the response filed 20 June 2005, applicant appears to contend that the recitation "consisting essentially of" excludes additional steps. However, applicant **did not show** that the characteristics of his invention would be materially changed by the addition of steps or materials. Applicant has not shown that the addition of a delivery unit would change the characteristics of his invention. Applicant merely pointed out that the device of Schwartz comprises a delivery unit and an insert. In addition, the delivery unit and insert of Schwartz still meets the limits of the claims if a closed definition of "consisting essentially of" is applied, since the delivery unit is part of a "cartilage repair structure" and may be seen as a part of the "cell-free matrix" as claimed by the applicant.

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R. Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3733

JRB
jrb

ENL
EDUARDO C. ROBERT
PRIMARY EXAMINER